United States Patent [19]

Nilson

[11] **4,325,369**

[45] **Apr. 20, 1982**

[54] **DISPOSABLE CONTAINER FOR A SYRINGE**

[75] Inventor: **Nils B. Nilson,** Mjölby, Sweden

[73] Assignee: **KeNova AB,** Malmo, Sweden

[21] Appl. No.: **169,429**

[22] Filed: **Jul. 16, 1980**

Related U.S. Application Data

[60] Division of Ser. No. 5,878,267, Feb. 16, 1978, Pat. No. 4,255,122, which is a continuation of Ser. No. 5,684,020, May 7, 1976, abandoned.

[51] **Int. Cl.**[3] **A61M 5/00**

[52] **U.S. Cl.** ..... **128/218 D**

[58] **Field of Search** ..... 128/216, 218 D, 232, 128/234, 215; 222/95, 107, 105, 215; 141/2, 23–27

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,688,964	9/1954	Smith	128/216
4,072,249	2/1978	Ekemstan et al.	128/232 X

FOREIGN PATENT DOCUMENTS

256696	9/1967	Austria	128/216
1103541	11/1955	France	128/216
114199	3/1926	Switzerland	128/216

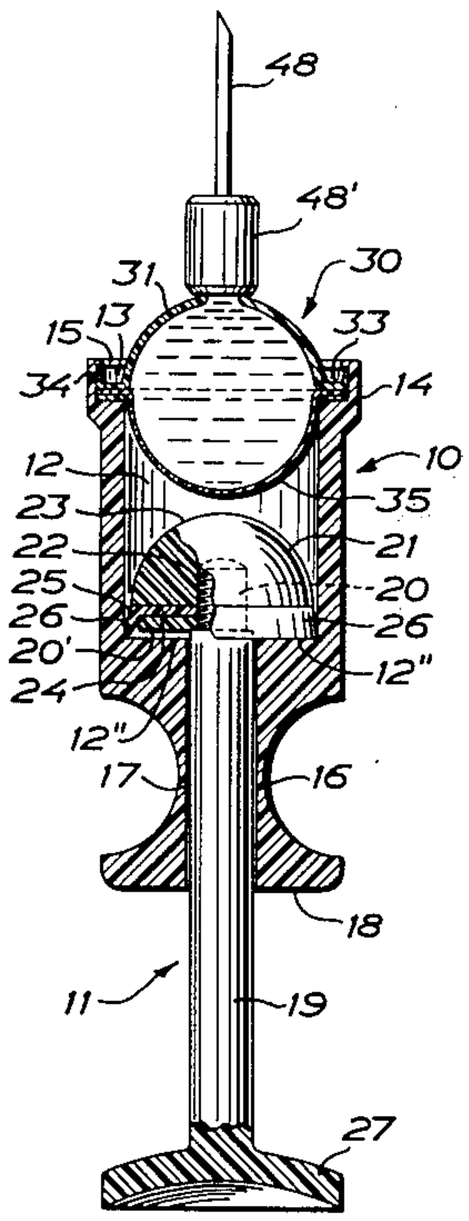
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Finnegan, Henderson, Farabow, Garrett & Dunner

[57] **ABSTRACT**

A disposable container for forming the end wall of the open end of a barrel of a syringe and for being retained thereon by the resilient interaction of a surface of the barrel and the resilient periphery of a circumferential flange at the intersection of a substantially rigid first wall portion and a flexible second wall portion of the container. Preferably the resilient periphery flexes when pressed into the barrel and then springs out to engage an annular channel-like area in the barrel.

1 Claim, 8 Drawing Figures



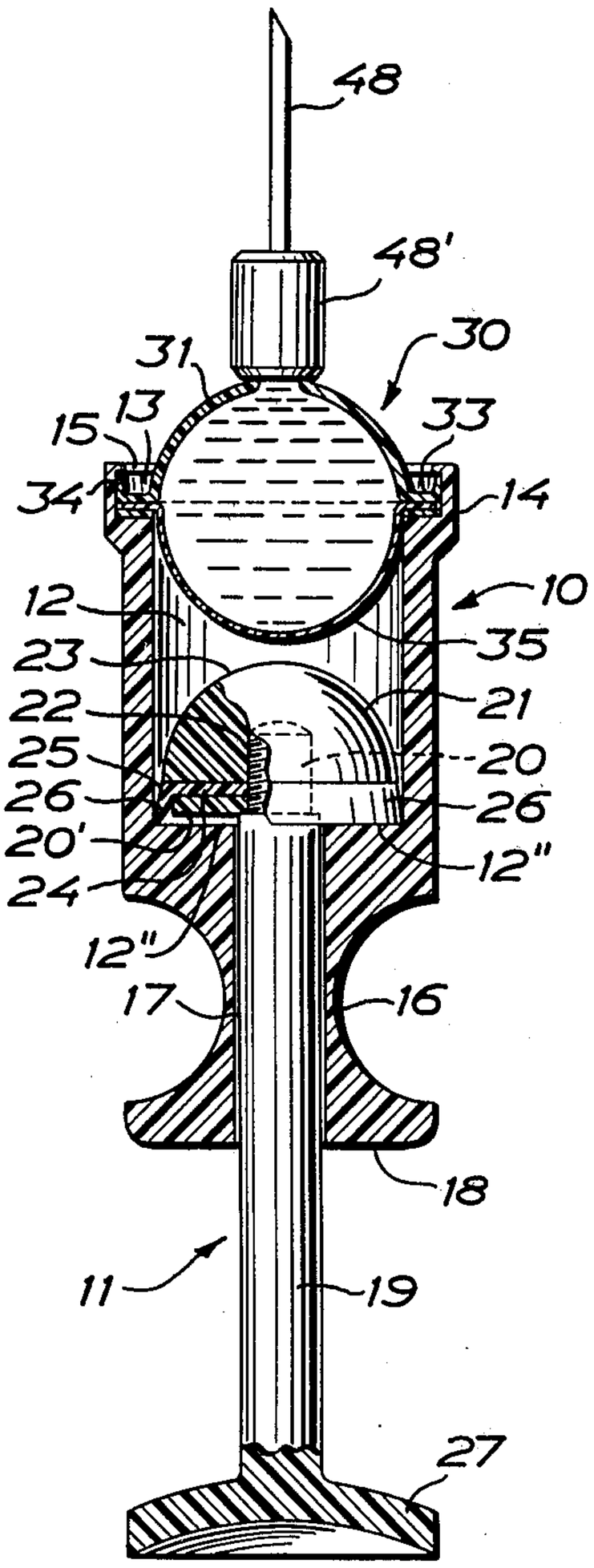

48
48'
31
30
13
15
33
34
14
10
12
35
23
21
22
25
20
26
26
20'
12"
24
12"
17
16
18
11
19
27

FIG. 1

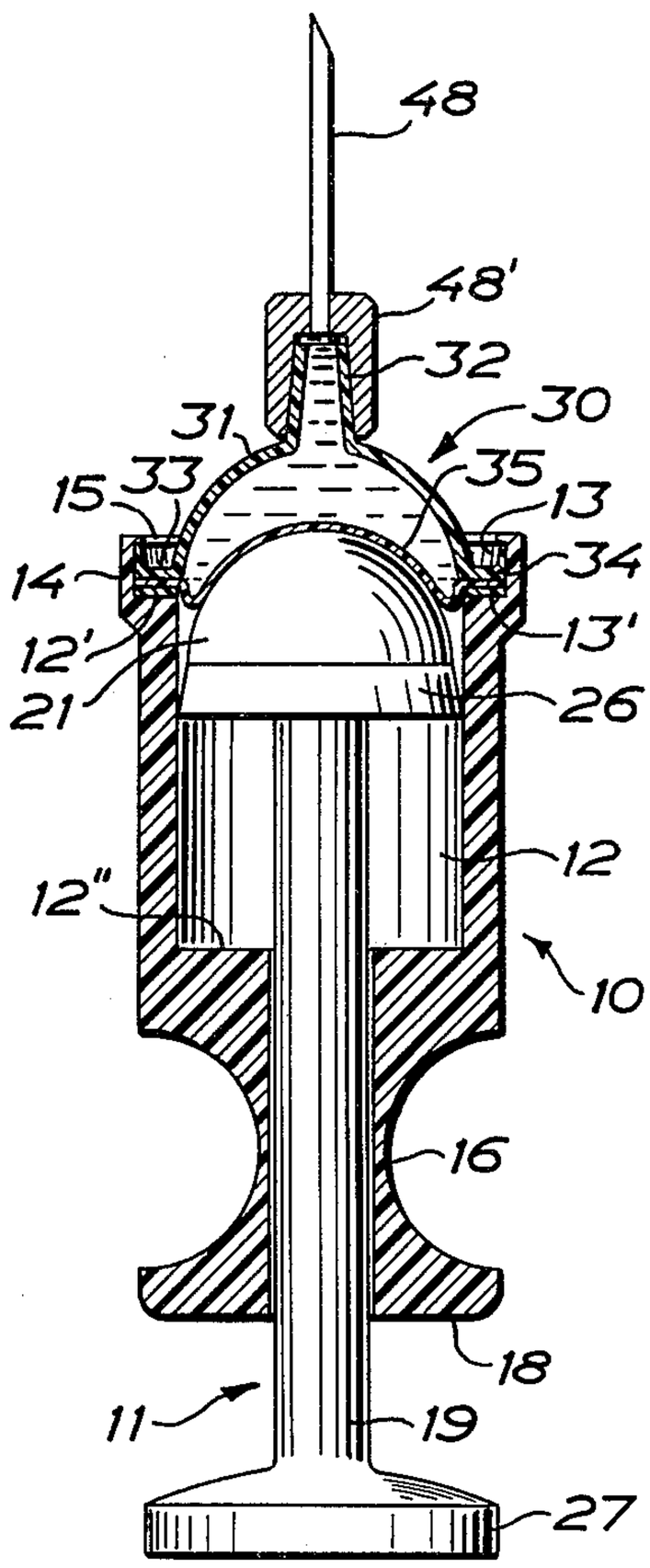

48
48'
32
31
30
33
35
15
13
14
34
12'
13'
21
26
12
12"
10
16
18
11
19
27

FIG. 2

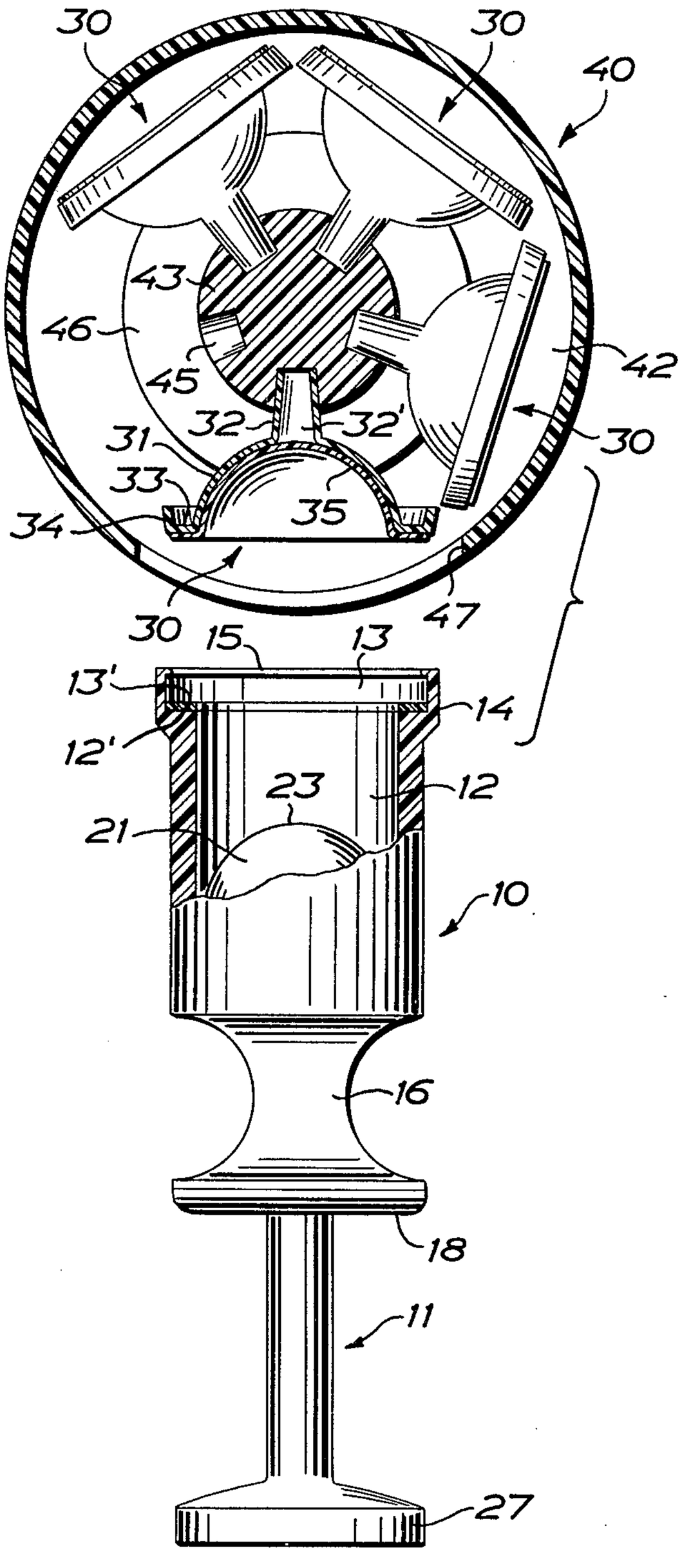

30
30
40
43
46
45
42
32
32'
31
30
33
35
34
30
47
15
13
13'
14
12'
12
23
21
10
16
18
11
27

FIG. 3

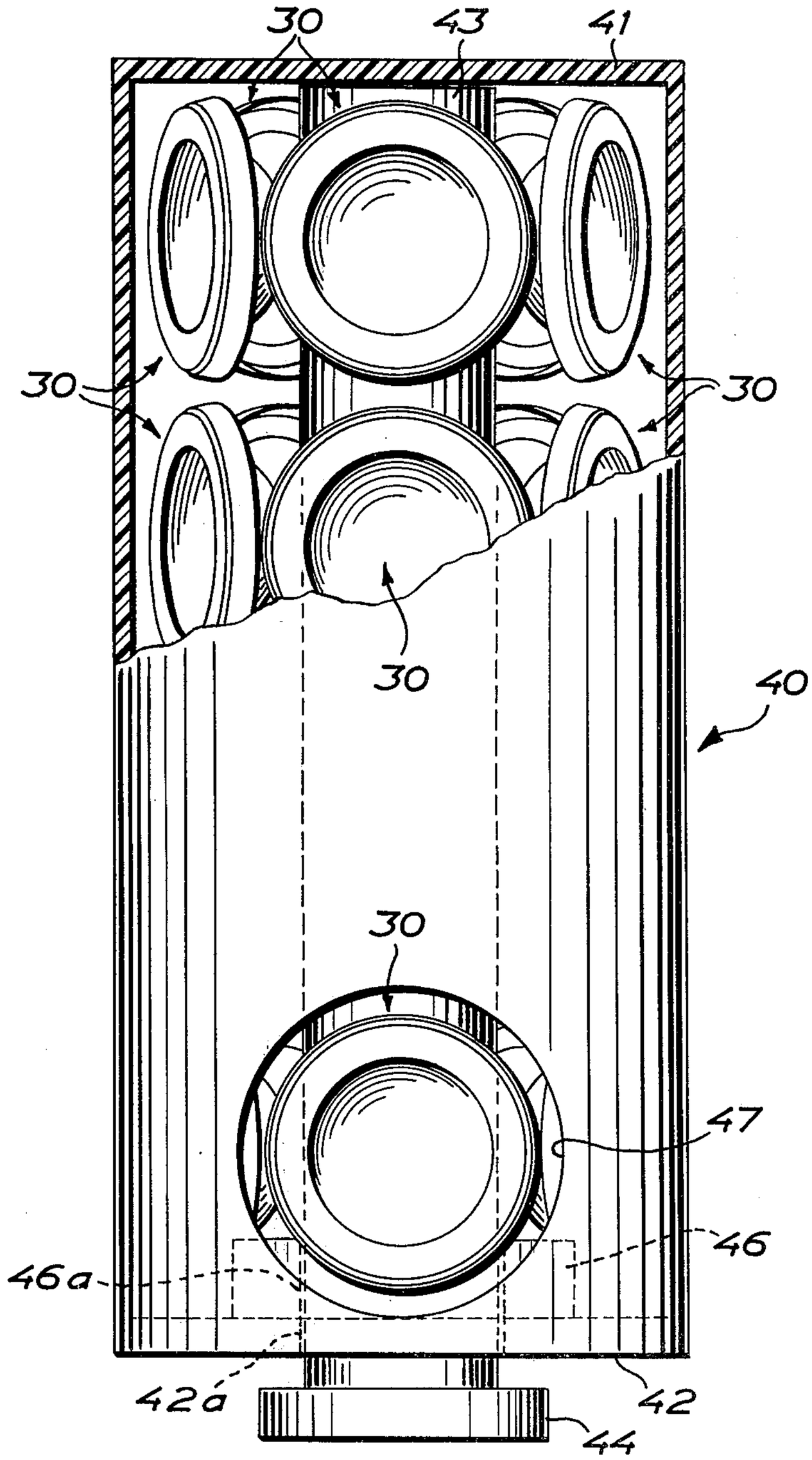


FIG. 4

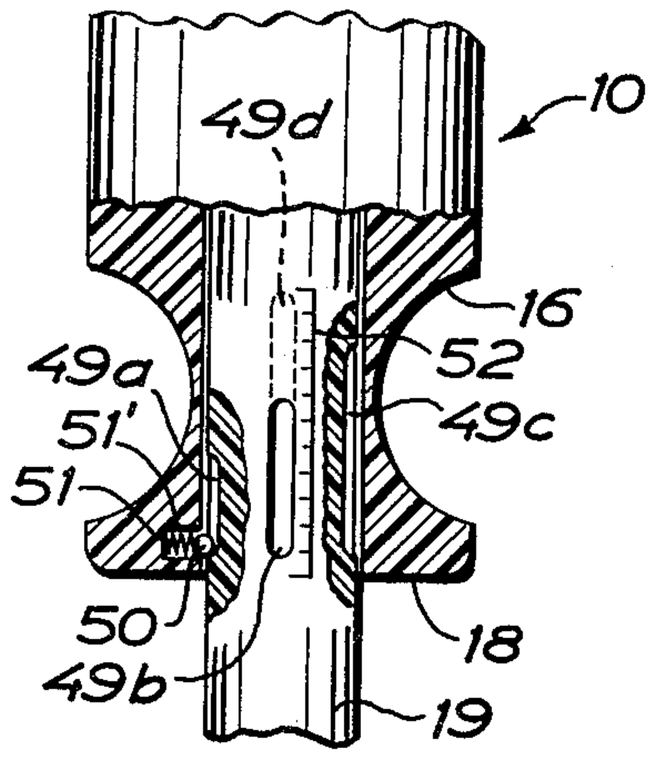


FIG. 5

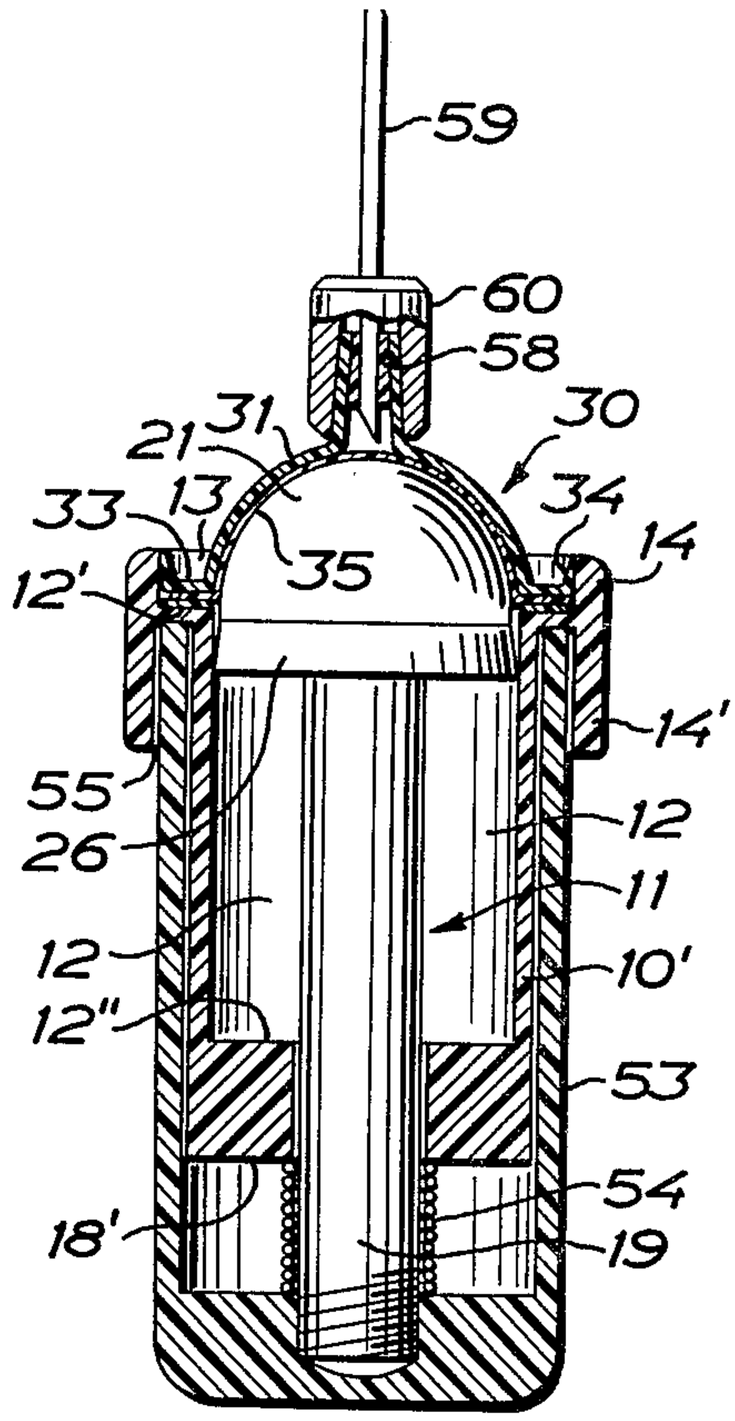


FIG. 6

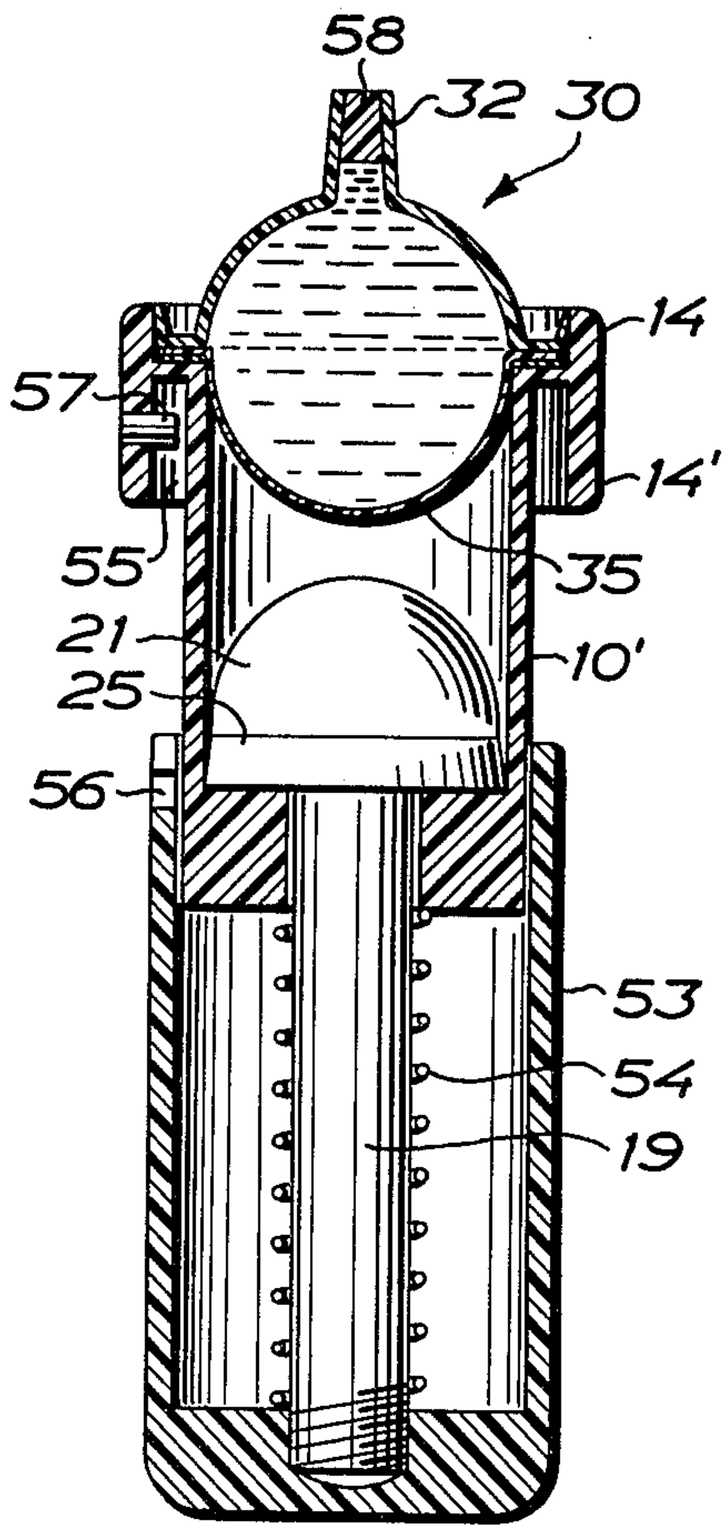


FIG. 8

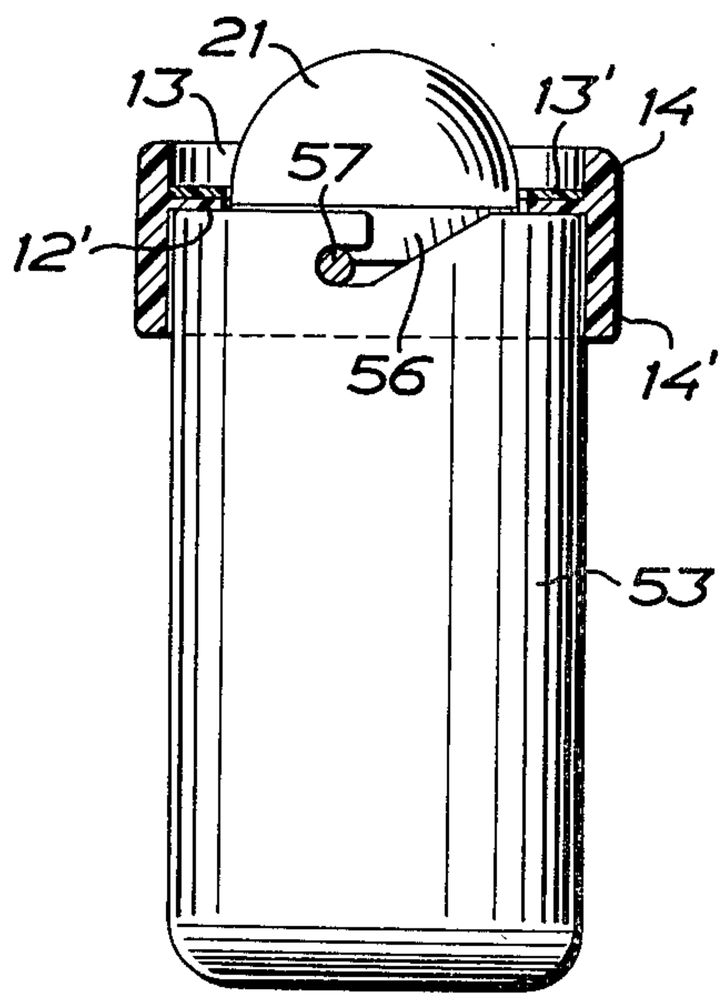


FIG. 7

DISPOSABLE CONTAINER FOR A SYRINGE

This is a division of application Ser. No. 878,267, filed Feb. 16, 1978, now U.S. Pat. No. 4,255,122, which is a continuation of Ser. No. 684,020, filed May 7, 1976, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to improvements in disposable containers for syringes for effecting subcutaneous and intramuscular injections of medicaments and the like into human beings and animals and for taking blood samples therefrom.

2. Description of the Prior Art

Most syringes now used in hospitals, offices and health centers are of the disposable type, that is, they are disposed of or discarded after one use. These syringes usually comprise two pieces—a barrel and a plunger or piston mounted for reciprocable movement in the barrel. Both parts are usually made of plastic material. The barrel has a nozzle at the discharge end for the attachment of a hypodermic needle or cannula. On the plunger a sealing ring of rubber material is provided to act as a seal between the plunger and the inside surface of the barrel. Either the barrel or the plunger is provided with a scale by which the volume of liquid drawn into or dispensed from the barrel may be accurately determined.

As a disposable product a syringe of this type, although made by modern mass production methods such as injection molding, is relatively expensive due to the materials and precision involved in the manufacture thereof. Considering the enormous number of disposable syringes used over the world each year, estimated at several billions, the cost and waste of material is significant and can hardly be justified. Any reduction in the manufacturing cost of a syringe, even if it amounts to only a fraction of a cent, can provide a large saving. Consequently, great efforts have been made and still are being made to lower the manufacturing costs of disposable syringes.

These efforts have not so far resulted in a radical change of the construction or the method of manufacturing of disposable syringes. They are still constructed as a two piece article which has to be thrown away in its entirety after having been used only once.

It has not been suggested so far to limit the disposable aspect to part of the syringe only; a readily apparent problem in connection therewith is the difficulty to maintain in a satisfactory manner the sterility of the syringe if a part thereof is to be used more than once.

It has been proposed to combine a barrel and a plunger with a replaceable container positioned at the discharge end of the barrel, the container being introverted or collapsed upon itself in use by action of the plunger to eject or administer the medicament contained in the container. Syringes of this type are disclosed in U.S. Pat. No. 978,488 to Roesch dated Dec. 13, 1910 and in U.S. Pat. No. 2,514,575 to Hein dated July 11, 1950. However, in these prior art syringes the container is a prefilled closed cartridge or capsule which is positioned in the barrel. The barrel is closed at the discharge end by a continuation of the barrel or by a separate end cap or like element. A discharge opening is provided at the discharge end to communicate with the attached needle or cannula.

A problem with this type of syringe is the possible contamination of the reusable elements following discharge of the cartridge or capsule contents. The expended cartridge or capsule must be withdrawn from the rear of the barrel or the end cap must be disconnected to permit cartridge or capsule removal. In either case, any contact of unexpended medicament with the reusable elements requires that these elements be cleaned and then sterilized. Additionally this type of syringe only permits discharge of the container contents and does not allow the medicament or the like to be drawn into the container under sterile conditions. This is a problem also for the injection apparatus disclosed in U.S. Pat. No. 3,308,818 to Rutkowski dated Mar. 14, 1967 wherein a container is located in a barrel which functions as a gas expansion chamber, and the container is introverted upon itself by gas pressure produced in said barrel by an explosive device.

SUMMARY OF THE INVENTION

The present invention overcomes the foregoing problems and disadvantages of the prior art by providing a syringe in which only a small part of the apparatus is discarded after each use, the rest of the syringe being used repeatedly, and wherein this can be achieved while maintaining a high degree of sterility and without contamination of the reusable portion.

Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

To achieve the foregoing objects and in accordance with the purpose of the invention, as embodied and broadly described herein, the disposable container of this invention for a syringe comprises a container adapted to form the end wall of the open discharge end of a barrel of a syringe, the container including a substantially rigid first wall portion having an inside surface; a flexible second wall portion introvertible upon the inside surface of the first wall portion; a nozzle on said first wall portion for attaching a hydodermic needle thereto, the first and second portions being formed into a unitary shell; and circumferential flange means integral with said shell substantially at the intersection of said first and second wall portions and having a resilient periphery for resiliently interacting with a surface of the open discharge end of the barrel of the syringe for retaining the container thereon.

The accompanying drawings, which are incorporated in and constitute part of this specification, illustrate one embodiment of the invention and, together with the description, serve to explain the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view partly in axial cross-section of the preferred embodiment of the syringe constructed according to the teachings of the invention, shown prior to the dispensing operation;

FIG. **2** is a view similar to FIG. **1** of the complete syringe, shown during the operation sequence;

FIG. **3** is a plan view partly in cross-section of the preferred embodiment of a syringe system constructed according to the teachings of the invention comprising a barrel and a reciprocable plunger together with a

magazine for storing under sterile conditions a large number of empty containers;

FIG. **4** is a side view, partly in cross-section of the magazine shown in FIG. **3**;

FIG. **5** is a fragmentary side view in cross-section of the syringe disclosing an embodiment for automatically controlling the amount of liquid to be drawn into or expelled from the syringe container;

FIG. **6** is a cross-sectional view of a second embodiment of the syringe constructed according to the teachings of the invention for withdrawing blood samples or other liquids;

FIG. 7 is a side view of the syringe shown in FIG. **6** with the container removed; and

FIG. **8** is a sectional view of the syringe shown in FIG. **6** after a liquid sample has been extracted.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings.

Referring to FIGS. **1** and **3** of the drawings which disclose in detail the construction of the syringe according to the teachings of the invention such syringe provides a two-part unit which is constructed for repeated use and comprises an elongated barrel **10** having a discharge end, and a plunger or piston **11** reciprocably mounted in the barrel. This barrel can be made as an integral element entirely of metal or a plastic material and preferably is made of a transparent material.

The barrel forms a cylindrical cavity **12** which widens at a shoulder **12'** into an enlarged cylindrical socket **13** at the discharge end of the barrel, said socket **13** being defined at its periphery by an integral wall **14**. On the shoulder there is positioned an annular sealing ring **13'** . At the edge of wall **14** there is formed on the inside surface thereof a circumferential, inwardly-directed rib or lip **15** preferably with a rounded profile. At the end opposite to the discharge end the barrel has a circumferential recess **16** having a concave or rounded shape which provides a finger grip by which the barrel may be grasped during the operation of the syringe. If desired, the bottom of the groove may be flattened.

The barrel forms a cylindrical passage **17** extending from the inner end or bottom **12''** of cavity **12** through the finger grip portion **16** and opening at the flat end surface **18** of the barrel. Plunger **11** comprises a cylindrical rod **19** which is received in passage **17** and is slidable therein. Clearance is provided between plunger **11** and passage **17** to allow air to pass between cavity **12** and the surrounding atmosphere.

Rod **19** forms a threaded inner end **20** on which is mounted a plunger head **21**, a threaded bottom hole **22** in the plunger head receiving the threaded end **20** of the rod. This plunger head also forms a hemispherical end surface **23** facing the discharge end at socket **13** of the barrel, and a flat base surface **24** facing the bottom **12''** of the barrel. Against the base surface **24** there is applied to the plunger head a sealing element **25** of a soft rubber material such as silicone rubber. The sealing element is clamped between a washer **20'** and the end surface of the plunger head and forms a conical lip or sleeve **26** which slopes outwardly and sealingly engages, due to the inherent elasticity thereof, the inside cylindrical surface of cavity **12**. The sealing element also acts as a valve member during the expulsion step as later described. At the external end of rod **19** this rod forms a disc **27** integral with the rod for manually operating the plunger.

A container or cartridge constructd to be removably attached to the discharge end of the barrel to form the end wall thereof is generally indicated at **30** and comprises a substantially rigid hemispherical first wall portion **31** at the exterior side of the end wall and having an inside surface. Said first wall portion forms an externally protruding centrally positioned nozzle **32** conically tapered towards the outer end thereof, for attaching a hypodermic needle or cannula thereto.

Means for removably attaching the container to the discharge end of the barrel comprises a circumferential flange **33** on the container which merges into a conical resilient rim **34**, see FIG. **3**, protruding outwardly in the same direction as nozzle **32** at one side of the flange. Said first wall portion **31** of container **30** may be made of a suitable plastic material. The container further comprises a flexible second wall portion **35** at the interior side of said end wall formed by the container when attached to the barrel. Said second wall portion is connected to the other side of flange **33** preferably by adhesive, melting or ultra sonic welding. Wall portion **35** preferably is made of a flexible plastic material. It is introvertible upon the inside surface of the first wall portion **31** to the collapsed position shown in FIG. **3**, and in this position said second wall portion **35** is seen to be dimensioned and formed so as to contact the concave inside surface of wall portion **31** of the empty container, following the curvature of said wall portion. This is the condition in which the container is delivered.

In the collapsed condition, the interior of the container is accessible through the passage **32'** of nozzle **32** and, therefore, the requirement of sterility is not met if the nozzle passage is left uncovered when the container is delivered. This passage has to be closed under sterile conditions and this is preferably made by delivering several containers in a magazine as shown in FIGS. **3** and **4**.

Referring to FIGS. **3** and **4** there is provided a cylindrical housing **40** having a closed end wall **41** and an end wall **42** centrally apertured at **42***a*. A cylindrical stem **43** passing through aperture **42***a* of end wall **42** and being rotatable and axially displaceable therein projects at one end thereof from the housing and is provided with a head **44** for the manipulation of the stem. Several annular sets of radial conical bottom holes **45** are formed in the stem at axially spaced levels thereof. These holes are each sized to receive nozzle **32** of a container **30** of the type described above and to permit retention of the nozzle by a slight press fit in the hole.

Thus, a plurality of empty containers are fitted to the stem arranged in axially spaced annular banks thereon, and in this position the interior of each container is closed from the surrounding. Consequently, the containers can be stored in this way in a sterile condition obtained e.g. by gamma radiation of the containers when fitted to the stem. The lowermost annular bank of containers rests against an apertured shoulder **46** formed centrally on the inside surface of wall **42**, the aperture **46***a* thereof being in registry with aperture **42***a*, and in this position the stem may be rotated to bring each of the containers in the lowermost bank of containers separately opposite an opening **47** in the cylindrical side wall of the housing for access by the barrel socket **13**.

When the lowermost annular bank of containers **30** has been removed from the magazine, stem **43** will be

lowered so that the next annular bank of containers will bear on shoulder **46** on the apertured end wall **42** to support the stem and the containers attached thereto. In this way each annular bank of containers is brought to the level of opening **47** by axial displacement of stem **43** and when brought to this level each of the containers of the lowermost bank of containers can be removed separately from the magazine through opening **47**.

Referring to FIG. **3** the removal of each container through opening **47** is effected by introducing barrel **10** at the discharge end thereof into opening **47** and by pushing socket **13** onto flange **33** and resilient rim **34** of the container which has been brought opposite opening **47** to receive the flange and rim in socket **13**. When the barrel is being slid over rim **34** forming the resilient periphery of the flange **33** to receive the rim in socket **13** the rim flexes or gives when sliding against rib or lip **15** and then, after having slipped over the rib or lip, springs out to engage at the edge thereof the inner side of the rib or lip. By the engagement thus obtained between the barrel and the container the container will be retained by the barrel and will be withdrawn from stem **43** by withdrawal of the barrel. A hypodermic needle or cannula **48** having a socket **48'** may be forcefitted manually to nozzle **32** of container **30** connected with the barrel and, thus, a complete and operable syringe has been formed.

If the plunger head **21** is not already contacting the concave outside surface formed by wall portion **35** collapsed against and following the curvature of the inside surface of wall portion **31** it is displaced manually to such position to contact wall portion **35**, the end surface of the plunger head being hemispherical to substantially conform to the inside surface of wall portion **35** when collapsed against wall portion **31**. When the plunger head is being moved towards the container at the discharge end of the barrel, said end being closed off by the container forming an end wall of the barrel, air enclosed in front of the moving plunger will pass between the plunger head and the cavity wall due to yielding of the conical lip or sleeve **26** of sealing element **25**. The atmosphere communicates with the interior of the barrel through the clearance around rod **19** in passage **17**.

Cannula **48** is then inserted in a bottle or the like containing a liquid medicament to be received by the container, or in a blood vessel in order to take a blood sample therefrom, as the case may be. As the plunger **11** is retracted the conical lip or sleeve **26** of sealing element **25** will sealingly engage the inside wall of the barrel due to the fact that it will be brought to expand towards that wall by the friction between the lip or sleeve and the wall. The part of cavity **12** enclosed between the plunger head and the inner end of the cavity is vented through the clearance formed around rod **19** in passage **17** so that no pressure builds up behind the plunger head. Thus, a subpressure (partial vacuum) will be created in cavity **12** between the plunger head and the end wall formed at the discharge end of the barrel by container **30** a leakproof seal being provided between the container and shoulder **12'** by sealing ring **13'**. No air will be able to pass into this space from the surrounding since an effective seal will be maintained also between plunger lip **26** and the inside surface of the barrel wall when the plunger is retracted from the discharge end as explained above. By the subpressure thus created wall portion **35** will be progressively withdrawn from wall portion **31** as shown in FIG. **2** and the container will be filled with liquid.

In operation, to eject the liquid from the container e.g. for administering the medicament or for transferring the blood sample to a test tube, as the case may be, the container is emptied by pressing the plunger head **21** against the filled container. During this operation needle **48** is inserted in a blood vessel or under the skin of a human being or an animal for administering the medicament, or alternatively in a test tube or other receiver to which the blood sample shall be transferred for treatment or test operations. The flexible wall portion **35** will be introverted mechanically by the hemispherical end surface **23** of plunger head **21** and will be collapsed against the inside surface of wall portion **31**. No overpressure is allowed to build up in front of the plunger head due to the valve action provided by the lip or sleeve **26** of sealing element **25** as described above. This is one of the important features of the syringe system according to the invention. If air under pressure trapped between the container and the plunger head were allowed to pass into the container through a perforation in a defective flexible wall portion **35** the air could arrive in a blood vessel which could be dangerous to the patient and even mortally, or build up of compressed air in front of the plunger head could eject the container from socket **13** of the barrel. If liquid leaks into the cavity **12** of barrel **10** from a defective container it could be contaminated by contacting the barrel and the plunger. Such contaminated liquid will pass to the back side of the plunger head at lip **26** where the flow resistance is lower than that in the cannula, and thus will not be administered from the syringe. This is a further safety feature of the syringe according to the teachings of the invention.

When the liquid in the container has been expelled therefrom, the emptied container can be ejected from the barrel by means of the plunger. An increased force is exerted manually on the flexible wall portion **35** which contacts wall portion **31** when the container has been emptied, and under the force thus exerted on the emptied container rim **34** is brought to yield and to disengage rib or lip **15**. The container is thrown away together with the cannula and a fresh container is attached to the barrel in the manner described. Thus it will be seen that only a small part of the complete syringe is provided as a disposable product to be thrown away after each use. This will considerably reduce the cost for each operation in relation to the common practice to throw away after each injection the entire syringe, thanks to the saving of material which also means that less waste has to be disposed of.

There may be provided on barrel **10** or on rod **19** a graduation or scale which is read against an index on the rod and the barrel, respectively, for reading the volume of liquid drawn into container **30**. Since the operative connection between wall portion **35** of container **30** and the plunger or piston head **21** during the suction stroke of the syringe is provided by the subpressure created in front of the plunger between the plunger head and the container, the increase of the interior volume of the collapsed container when wall portion **35** is moved away from wall portion **31** will be the same volume as that displaced by plunger head **21** in the cylindrical cavity **12**. This means that the graduation or scale wil be linear.

It is possible to have containers of different size for co-operation with one and the same barrel so that a

number of standard volumes can be chosen by choosing a container of the desired volume, although different sized barrels may be used for containers of different size. Other volumes than standard volumes may be determined by means of the graduation and the index against which such graduation is read.

FIG. **5** discloses an arrangement by which a container **30** can be filled with liquid to a predetermined extent without reading a graduation. In rod **19** there are provided four axially extending grooves **49***a*, **49***b*, **49***c* and **49***d* which are spaced apart ninety degrees about the axis of rod **19**. These grooves are of different length and they have all the end adjacent disc **27** in a common transverse plane of the rod. A detent formed by a ball **50** is biased by a pressure spring **51** received by a cavity **51'** formed in the barrel, the ball thus being pressed against rod **19**. This rod may be rotated in passage **17** to bring one of the grooves into register with the ball. Such rotation takes place against the resistance offered by ball **50** when it is forced out of the groove in which it is received at the time, against the bias provided by spring **51**. In FIG. **5** the ball is received by groove **49***a*. When the plunger is displaced axially the ball rides in the groove and offers increased resistance to movement beyond the ends of the groove to indicate the length of the stroke defined by the groove cooperating with the ball. When the plunger is being displaced for sucking liquid into the container attached to the barrel, the ends of the axial distance represented by a groove such as groove **49***a* will be felt as a pressure point at each end of the axial distance represented by the groove. The length of each groove may be adjusted to correspond to a predetermined volume of liquid in the container. If a greater volume is desired rod **19** may be rotated in order to bring the proper groove into register with ball **50**. It is possible to adjust the volume by means of a graduation **52** provided on rod **19**, end wall **18** of the barrel forming an index for reading such graduation, in case it is wanted to fill the container to an extent which does not correspond to one of the standard volumes represented by the grooves. The longest groove **49***d* should preferably correspond to complete filling of the container.

In FIGS. **6** to **8** there is disclosed an embodiment of the invention which has been developed preferably to assist in taking blood samples from a human being or an animal. In this case there is provided on barrel **10'** a socket or sleeve **53** having an open end. The barrel slides telescopically in and is received by this sleeve which at the other closed end is connected to the outer end of rod **19**. Between the end surface **18'** of the barrel and the bottom of sleeve **53** there is arranged a helical compressed spring **54** biasing the barrel and the sleeve to extend the barrel from the open end of sleeve as disclosed in FIG. **8**. As in the previous embodiment there is provided a socket **13** receiving flange **33** and rim **34** of a container **30** but in this case there is no rib such as rib **15** in FIGS. **1** to **3** provided on the inside surface of the side wall **14** of socket **13**. Since the syringe in this embodiment of the invention is adapted for sucking liquid into the container when a blood sample is being taken but not for expelling the blood from the container when connected with the barrel the frictional engagement between resilient rim **34** and the inside of the wall **14** is sufficient to maintain the container on the barrel the more so as the subpressure created between the container and the plunger head when the plunger is withdrawn forces the container to be pressed against sealing ring **13'** on shoulder **12'**. Socket **13** is extended at **14'** to form together with the rest of barrel **10'** an annular groove **55** for receiving sleeve **53** as shown in FIG. **6**, which can be brought to this position by displacing plunger head **21** towards the discharge end of barrel **10'** by movement of the barrel within sleeve **53** against the action of spring **54** thereby compressing the spring. For arresting sleeve **53** in this position there is provided in the sleeve a notch **56** of the form disclosed in FIG. **7** and there is provided on socket extension **14'** a pin **57** extending radially inwardly which may be brought into engagement with notch **56** by introducing the pin into the notch when sleeve **53** is pressed against the discharge end of barrel **10'** and then rotating the sleeve so that the condition disclosed in FIG. **7** will be obtained.

In this case there is provided in nozzle **32** a stopper **58** of a soft rubber material which is designed to be penetrated by a double-ended cannula **59** manually fitted to the nozzle by an attachment **60**. This cannula is inserted into the blood vessel and then sleeve **53** is rotated in order to disengage it from pin **57**. When the sleeve is released it will be displaced in relation to barrel **10'** by means of spring **54**, the plunger thereby being retracted or withdrawn in barrel **10'** in order to draw the blood into container **30** in the manner described with reference to the embodiment disclosed in FIGS. **1** to **5**, the movement of the plunger being accomplished automatically by means of spring **54**, not manually as in FIGS. **1** to **5**.

Once the container has been filled with blood the cannula may be removed from the nozzle. Stopper **58** will close automatically the passage through the nozzle. The container may be removed from the barrel manually in order to be transferred to a laboratory or to a storage freezer for future use.

The double-ended cannula **59** may be provided with well-known valve means (not shown) in order to close off the passage through the cannula when it is withdrawn from the container. Such valve means are disclosed e.g. in U.S. Pat. Nos. 3,469,572 to Nehring and 3,585,984 to Buchanan. Thus, several blood samples may be taken through one and the same cannula with only one penetration of the blood vessel.

It will be apparent to those skilled in the art that various modifications and variations could be made in the syringe of the invention and in the container forming part thereof without departing from the scope or spirit of the invention.

What is claimed is:

1. A container adapted to form the end wall of the open discharge end of a barrel of a syringe, the container comprising:

a substantially rigid first wall portion having an inside surface;

a flexible second wall portion introvertible upon the inside surface of the first wall portion;

a nozzle on said first wall portion for attaching a hypodermic needle thereto, said first and second portions being formed into a unitary shell; and

circumferential flange means integral with said shell substantially at the intersection of said first and second wall portions and having a resilient periphery for resiliently interacting with a surface of the open discharge end of the barrel of the syringe for retaining the container thereon.

* * * * *